Stanley D. Harpstead
1277 Nursery Hill Lane
Arden Hills, MN 55112-5752
(612) 604 - 9097
SHarpstead@aol.com

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Ref. Docket Number OOP-0788

Dockets Management Branch (HFA – 305)
Food and Drug Administration
9200 Corporate Blvd.
Rockville, MD 20850

I am writing in response to the reclassification of the Totally Implanted Spinal Cord Stimulation (SCS) Devices for treatment of chronic pain conditions. To begin, I must admit I am potentially biased as I used to work at Medtronic Inc. (1990 to 1995) and I still own Medtronic stock. Since that time I have been pursuing a PhD in Neuroscience at the University of Minnesota.

The transition of an implanted device from a PMA requirement to the general controls found in a 510k application may have a significant unintended impact. There may be little risk with the current suppliers of these devices or even within the currently approved therapy applications. The risk that I am concerned with is the lowering of the approval threshold that may let these devices to be used for "off-label" applications. The range of programmable parameters found in the current SCS stimulators would be acceptable for most of the potential "off label" applications when connected to a lead system placed in proximity to the targeted neural site.

As you know a variety of neuromodulatory and potentially therapeutic applications have been demonstrated/proposed. These include: pain therapy for radicular neuropathic pain (using either peripheral nerves or dorsal columns); sacral nerve stimulation for treatment of voiding dysfunctions; sacral nerve stimulation for treatment of fecal incontinence (European reference); dorsal column stimulation for treatment of peripheral vascular disease and chronic angina (European references); direct muscle stimulation for preservation of muscle during nerve re-implantation (Canadian reference); vagal nerve stimulation for treatment of epilepsy (approved), depression, obesity and Alzheimer's (under investigation?); phrenic nerve stimulation of respiratory support; thalamic and globus pallidus stimulation for movement disorders. The list will probably only be limited by the number of potential neural sites and the potential neural pathways that interact with these sites. In summary the number of interesting targets will continue to expand.

At this time it would be prudent to have a "higher" threshold for approval of these SCS devices to minimize the potential for "off label" explorations. The PMA process requires a substantial investment in gathering relevant data in a prospective and unbiased fashion for each indication. As a direct result, there is a significantly different corporate culture and investment in regulatory compliance in those companies that have had experience with PMA applications, than that found in companies that only supply 510k devices. Hopefully these cultural differences and increased compliance will cause all "off label" applications to properly proceed through the mandated FDA approval processes.

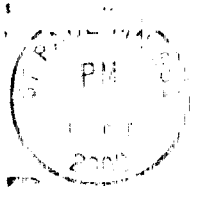
On the other hand if the reclassification of the device were designed such that it had limited potential for "off label" forays and a long history of use, I think it would be appropriate to reclassify the device, reducing approval times, increasing competition and providing alternatives for the medical community. In my opinion the current nerve stimulation devices and many potential therapeutic applications do not meet these limitations. A lower threshold for approval of nerve stimulation devices will not be in the best long-term interest of the American public.

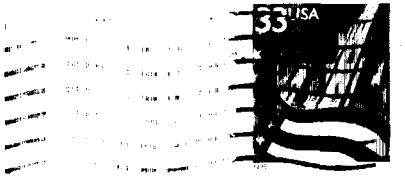
Please feel free to call me if you have any questions regarding my position.

Best Wishes,

Stanley D. Harpstead

The Harpstead's
1277 Nursery Hill Ln
Arden Hills, MN 55112





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